

WE CLAIM:

1. A method for delivering at least one therapeutic agent to a patient in need thereof comprising contacting patient mucosa with a formulation comprising:
 - 5 a) a composition selected from the group consisting of synthetic cervical mucus, synthetic vaginal fluid, and both synthetic cervical mucus and synthetic vaginal fluid, and,
 - b) at least one therapeutic agent.
2. The method of claim 1, wherein the mucosa is vaginal or rectal.
- 10 3. The method of claim 1, wherein the patient is human and the therapeutic agent is N-[4-chloro-3-(3-methyl-2-butenyloxy)phenyl] (UC-781) or a derivative thereof.
4. The method of claim 3, wherein the UC-781 is present in the formulation from at least
15 about 0.001% to at least about 1.0% wt %.
5. The method of claim 1, wherein at least one therapeutic agent is selected from the group consisting of hormones, anti-microbial agents, anti-viral agents, analgesic agents and anaesthetic agents.
- 20 6. The method of claim 1, wherein the formulation is topically administered.
7. The method of claim 1, wherein the composition in step a) comprises the synthetic mucus and the synthetic vaginal fluid in a ratio which is optimal for delivery of at least one
25 therapeutic agent.
8. The method of claim 1 wherein the synthetic vaginal fluid has at least two properties equal to, or substantially identical to, the properties of a composition comprising: NaCl, 3.51 g/L; KOH, 1.40 g/L; Ca(OH)₂ 0.222 g/L; serum albumin, 0.018 g/L; lactic acid, 2.0 g/L;
30 acetic acid, 1.0 g/L; glycerol, 0.16 g/L; urea 0.4 g/L; and glucose, 5.0 g/L; wherein the composition has a pH of about 4.2;
the properties selected from the group consisting of: pH, osmolarity and surface tension.

9. The method of claim 1 wherein the synthetic vaginal fluid has the following composition: NaCl, 3.51 g/L; KOH, 1.40 g/L; Ca(OH)₂ 0.222 g/L; serum albumin, 0.018 g/L; lactic acid, 2.0 g/L; acetic acid, 1.0 g/L; glycerol, 0.16 g/L; urea 0.4 g/L; and glucose, 5.0 g/L; wherein the composition has a pH of 4.2.
10. The method of claim 1, wherein the composition in step a) is synthetic cervical mucus comprising a viscosity which is optimal for delivery of at least one therapeutic agent.
- 10 11. The method of claim 1, wherein the viscosity of the synthetic cervical mucus is from about 2,000 cP to about 10,000 cP.
12. The method of claim 1, wherein the synthetic cervical mucus comprises guar gum present at about 1.00% w/w; and, dried gastric mucin (type III) present at about 0.50 % w/w
- 15 wherein the guar gum is cross-linked with borate.
13. The method of claim 12, wherein the synthetic cervical mucus further comprises imidurea, present at about 0.30 % w/w; methylparaben, present at about 0.15 % w/w; and, propylparaben, present at about 0.02 % w/w.
- 20 14. The method of claim 13 wherein the synthetic cervical mucus further comprises dibasic potassium phosphate, present at about 0.26 % w/w; and, monobasic potassium phosphate, present at about 1.57% w/w.
- 25 15. A method for treating or preventing a disease comprising contacting mucosa of a patient in need thereof with a formulation comprising:
- a) a composition selected from the group consisting of: a composition comprising synthetic cervical mucus, a composition comprising synthetic vaginal fluid, and a composition comprising both synthetic cervical mucus and synthetic vaginal fluid, and,
- 30 b) an amount of at least one therapeutic agent effective to treat or prevent the disease.
16. The method of claim 15 wherein the mucosa is vaginal or rectal.

17. The method of claim 15, wherein the patient is human and the therapeutic agent is N-[4-chloro-3-(3-methyl-2-butenyloxy)phenyl] (UC-781) or a derivative thereof
18. The method of claim 17 wherein the UC-781 is present in the formulation from at
5 least about 0.001% to at least about 1.0% wt %.
19. The method of claim 15 wherein at least one therapeutic agent is selected from the group consisting of hormones, anti-microbial agents, anti-viral agents, analgesic agents and anaesthetic agents.
- 10 20. The method of claim 15, wherein the formulation is topically administered.
21. The method of claim 15, wherein the composition in step a) comprises the synthetic mucus and the synthetic fluid in a ratio which is optimal for delivery of at least one
15 therapeutic agent.
22. The method of claim 15 wherein the synthetic vaginal fluid has at least two properties equal to, or substantially identical to, the properties of a composition comprising: NaCl, 3.51 g/L; KOH, 1.40 g/L; Ca(OH)₂ 0.222 g/L; serum albumin, 0.018 g/L; lactic acid, 2.0 g/L;
20 acetic acid, 1.0 g/L; glycerol, 0.16 g/L; urea 0.4 g/L; and glucose, 5.0 g/L; wherein the composition has a pH of about 4.2;
the properties selected from the group consisting of: pH, osmolarity and surface tension.
- 25 23. The method of claim 15 wherein the synthetic vaginal fluid has the following composition: NaCl, 3.51 g/L; KOH, 1.40 g/L; Ca(OH)₂ 0.222 g/L; serum albumin, 0.018 g/L; lactic acid, 2.0 g/L; acetic acid, 1.0 g/L; glycerol, 0.16 g/L; urea 0.4 g/L; and glucose, 5.0 g/L; wherein the composition has a pH of 4.2.
- 30 24. The method of claim 15, wherein the composition in step a) is synthetic cervical mucus comprising a viscosity which is optimal for delivery of at least one therapeutic agent.

25. The method of claim 15, wherein the viscosity of the synthetic cervical mucus is from about 2,000 cP to about 10,000 cP.
26. The method of claim 15, wherein the synthetic cervical mucus comprises guar gum
5 present at about 1.00% w/w; and, dried gastric mucin (type III) present at about 0.50 % w/w, wherein the guar gum is cross-linked with borate.
27. The method of claim 26, wherein the synthetic cervical mucus further comprises imidurea, present at about 0.30 % w/w; methylparaben, present at about 0.15 % w/w; and,
10 propylparaben, present at about 0.02 % w/w.
28. The method of claim 27, wherein the synthetic cervical mucus further comprises dibasic potassium phosphate, present at about 0.26 % w/w; and, monobasic potassium phosphate, present at about 1.57% w/w.
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29. A method for delivery of an effective amount of at least one therapeutic agent to a mucosal surface of a subject comprising administering a formulation to the mucosal surface wherein the formulation comprises guar gum present at about 1.00% w/w, dried gastric mucin (type III) present at about 0.50 % w/w and a therapeutic agent present in an amount
20 sufficient to be effective when the formulation is administered.
30. The method of claim 29, wherein the mucosal surface is vaginal or rectal.
31. The method of claim 29, wherein the formulation further comprises imidurea, present
25 at about 0.30 % w/w; methylparaben, present at about 0.15 % w/w; and, propylparaben, present at about 0.02 % w/w.
32. The method of claim 31, wherein the formulation further comprises dibasic potassium phosphate, present at about 0.26 % w/w; and, monobasic potassium phosphate, present at
30 about 1.57% w/w.
33. The method of claim 29, wherein the subject is human and the therapeutic agent is N-[4-chloro-3-(3-methyl-2-butenyloxy)phenyl] (UC-781) or a derivative thereof.

34. The method of claim 33, wherein the UC-781 is present in the formulation from at least about 0.001% to at least about 1.0% wt %.
- 5 35. The method of claim 29, wherein at least one therapeutic agent is selected from the group consisting of hormones, anti-microbial agents, anti-viral agents, analgesic agents and anaesthetic agents.
36. The method of claim 29, wherein the formulation is topically administered.
- 10 37. The method of claim 29, wherein the formulation further comprises synthetic vaginal fluid in an amount sufficient for optimal delivery by the formulation of at least one therapeutic agent.
- 15 38. The method of claim 29 wherein the synthetic vaginal fluid has at least two properties equal to, or substantially identical to, the properties of a composition comprising: NaCl, 3.51 g/L; KOH, 1.40 g/L; Ca(OH)₂ 0.222 g/L; serum albumin, 0.018 g/L; lactic acid, 2.0 g/L; acetic acid, 1.0 g/L; glycerol, 0.16 g/L; urea 0.4 g/L; and glucose, 5.0 g/L; wherein the composition has a pH of about 4.2;
- 20 the properties selected from the group consisting of: pH, osmolarity and surface tension.
39. The method of claim 29 wherein the synthetic vaginal fluid has the following composition: NaCl, 3.51 g/L; KOH, 1.40 g/L; Ca(OH)₂ 0.222 g/L; serum albumin, 0.018 g/L; lactic acid, 2.0 g/L; acetic acid, 1.0 g/L; glycerol, 0.16 g/L; urea 0.4 g/L; and glucose, 5.0 g/L; wherein the composition has a pH of 4.2.
- 25 40. A method of producing a synthetic fluid composition wherein the synthetic fluid composition comprises properties substantially identical to naturally occurring vaginal fluid, the method comprising adding synthetic cervical mucus in an effective amount to a synthetic vaginal fluid to alter properties of the synthetic vaginal fluid to those substantially identical to the naturally occurring vaginal fluid.
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41. The method of claim 40, wherein the properties of the naturally occurring vaginal fluid are selected from the group consisting pH, osmolarity and surface tension .
42. The method of claim 40, wherein the synthetic fluid composition further comprises at
5 least one therapeutic agent.
43. The method of claim 40, wherein the therapeutic agent is N-[4-chloro-3-(3-methyl-2-butenyloxy)phenyl] (UC-781) or a derivative thereof.
- 10 44. A formulation comprising:
a) a composition selected from the group consisting of synthetic cervical mucus, synthetic vaginal fluid; and synthetic cervical mucus and synthetic vaginal fluid; and,
b) at least one therapeutic agent.
- 15 45. The formulation of claim 44 wherein at least one pharmaceutical agent is selected from the group consisting of hormones, anti-microbial agents, anti-viral agents, analgesic agents and anaesthetic agents.
46. The formulation of claim 44 wherein at least one therapeutic agent is UC-781 or a
20 derivative thereof.
47. The formulation of claim 44, wherein the viscosity of the synthetic cervical mucus is from about 2,000 cP to about 10,000 cP.
- 25 48. The formulation of claim 44, wherein the synthetic cervical mucus comprises guar gum present at about 1.00% w/w; and, dried gastric mucin (type III) present at about 0.50 % w/w, wherein the guar gum is cross-linked with borate.
49. The formulation of claim 48, wherein the synthetic cervical mucus further comprises
30 imidurea, present at about 0.30 % w/w; methylparaben, present at about 0.15 % w/w; and, propylparaben, present at about 0.02 % w/w.

50. The formulation of claim 49, wherein the synthetic cervical mucus further comprises dibasic potassium phosphate, present at about 0.26 % w/w; and, monobasic potassium phosphate, present at about 1.57% w/w.

- 5 51. The formulation of claim 44 wherein the synthetic vaginal fluid has at least two properties equal to, or substantially identical to, the properties of a composition comprising: NaCl, 3.51 g/L; KOH, 1.40 g/L; Ca(OH)₂ 0.222 g/L; serum albumin, 0.018 g/L; lactic acid, 2.0 g/L; acetic acid, 1.0 g/L; glycerol, 0.16 g/L; urea 0.4 g/L; and glucose, 5.0 g/L; wherein the composition has a pH of about 4.2;
- 10 the properties selected from the group consisting of: pH, osmolarity and surface tension.

52. The formulation of claim 44 wherein the synthetic vaginal fluid has the following composition: NaCl, 3.51 g/L; KOH, 1.40 g/L; Ca(OH)₂ 0.222 g/L; serum albumin, 0.018 g/L; lactic acid, 2.0 g/L; acetic acid, 1.0 g/L; glycerol, 0.16 g/L; urea 0.4 g/L; and glucose, 5.0 g/L; wherein the composition has a pH of 4.2.
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